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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/518,076	03/03/2000	Leland Shapiro	114232.109	5437

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EXAMINER

HILL, MYRON G

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 02/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/518,076

Applicant(s)

SHAPIRO, LELAND

Examiner

Myron G. Hill

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 November 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1- 39 is/are pending in the application.
- 4a) Of the above claim(s) 9- 11 and 16- 39 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1- 8 and 12- 15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 March 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>11/7/03</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This action is in response to amendment filed 7 November 2003.

Claims 1- 8 and 12- 15 are under consideration.

Information Disclosure Statement

A signed and initialed copy of IDS paper dated November 7, 2003 is enclosed.

Drawings

The drawings filed 3 March 2000 are accepted by the Draftsman.

Sequence Requirements

Applicant has amended the specification and the specification now complies with the Sequence Rules.

Rejections Withdrawn

Claim Rejections - 35 USC § 112

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of claims 1, 3, 5, 6, and 11 under 35 U.S.C. 112, second paragraph, is withdrawn.

Applicant's explanation of the meaning of the terms overcomes the rejection.

Claim Rejections - 35 USC § 102

The rejection of claims 1, 2, 5- 8, 11- 14 under 35 U.S.C. 102(b) as being anticipated by Lezdey (US 5,532,215) is withdrawn.

The rejection is withdrawn because the art no longer applies to the claims as amended.

Claim Rejections - 35 USC § 103

The rejection of claims 3 and 4 under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Gyorkos (US 5,618,852) is withdrawn.

The rejection is withdrawn because the art no longer applies to the claims as amended.

The rejection of claim 15 under 35 U.S.C. 103(a) as being unpatentable over Lezdey as applied to claims 1- 3, 5- 8, 11- 14 above, and further in view of Gyorkos (US 5,891,792) is withdrawn.

The rejection is withdrawn because the art no longer applies to the claims as amended.

Objection Maintained

Claim Objections

The objection of claim 15 is maintained.

Applicant states that the claim has been amended to fix the errors.

In claim 15 it appears that the first two punctuation errors were fixed but no editing marks are present to show the amendment. Also, at least in lines 25- 26, new text has been added without indication.

New Rejections Necessitated by Amendment

Claim Rejections - 35 USC § 103

Claims 1, 2, 5- 8, 11- 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lezdey (US 5,532,215) and Gosselin *et al.* (US 5627185).

Lezdey teaches a method to treat a subject suffering from a herpes virus infection, eczema or related conditions with an AAT compound by topical or systemic dosing at about 1mg/kg body weight (column 5, lines 16- 33, column 6, line 32 – column 7, Example 1, column 12, lines 10- 12, Claims 1 and 2). Lezdey teaches that AAT is a serine proteinase inhibitors that is in the subgroup called serpins (column 3, lines 39- 41) and that alpha 1- protease inhibitor (alpha 1- PI) is another name for AAT (column 5, line 19).

Gosselin *et al.* teach that acyclovir is known to have anti-Herpes activity (column 1, lines 39- 42).

One of ordinary skill in the art at the time of invention would have combined the treatments of Lezdey and Gosselin *et al.* with the expectation of at least additive effect of the two treatments.

Thus, it would be *prima facie* obvious to combine the treatments of Lezdey and Gosselin *et al.* with the expectation of at least additive effect of the two treatments.

Claims 1, 3 and 4 are rejected under 35 U.S.C. 103(a) as unpatentable over Gyorkos (US 5,618,852) and Gosselin *et al.* (US 5627185).

Gyorkos teaches AAT related compounds can be used to treat conditions that are caused by an imbalance in the level of alpha 1- PI including invasion of malignant tumors and related conditions (column 1, lines 28- 35). While Gyorkos does not name all the conditions as per the claims, one of skill in the art would realize the range of conditions that can be treated by the method of Gyorkos.

Gosselin *et al.* teach that acyclovir is known to have anti-Herpes activity (column 1, lines 39- 42).

One of ordinary skill in the art at the time of invention would have combined the treatments of Gyorkos and Gosselin *et al.* with the expectation of at least additive effect of the two treatments.

Thus, it would be *prima facie* obvious to combine the treatments of Lezdey and Gosselin *et al.* with the expectation of at least additive effect of the two treatments.

Claims 1 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lezdey in view of Gyorkos (US 5,891,792) and Gosselin *et al.* (US 5627185).

Lezdey teaches a method to treat a subject suffering from a herpes virus infection, eczema or related conditions with an AAT compound by topical or systemic dosing at about 1mg/kg body weight (column 5, lines 16- 33, column 6, line 32 – column 7, Example 1, column 12, lines 10- 12, Claims 1 and 2). Lezdey teaches that AAT is a serine proteinase inhibitors that is in the subgroup called serpins (column 3, lines 39- 41) and that alpha 1- protease inhibitor (alpha 1- PI) is another name for AAT (column 5, line 19).

Lezdey does not teach related compounds that have AAT-like activity.

Gyorkos teaches a series of compounds including (Benzyloxycarbonyl)-L-valyl-N-[1-(2-[-(3-methylbenzyl)-1,3,4-oxydioxolyl]carbonyl)-2-(S)-methylpropyl]-L-prolinamide that are serine proteinase inhibitors that are low molecular weight, high stability, stability in physiological conditions, is a serpin, and can be formulated as a pharmaceutical (column 11, line 60- column 12, line 9, column 13, line 34- column 14, line 47, and Example I). Gyorkos also teaches that these compounds are inhibitors of alpha-1 protease (column 1, lines 8- 53).

Gosselin *et al.* teach that acyclovir is known to have anti-Herpes activity (column 1, lines 39- 42).

One of ordinary skill in the art at the time of the invention would have known that the compounds described by Gyorkos had the activity exhibited by mammalian alpha-1-antitrypsin that are required to meet the requirements of the method of Lezdey. One of ordinary skill in the art at the time of the invention would have known the benefits of the compounds taught by Gyorkos as discussed above and would have used them in the method of Lezdey.

One of ordinary skill in the art at the time of invention would have combined the treatments of Lezdey in view of Gyorkos and Gosselin *et al.* with the expectation of at least additive effect of the two treatments.

Thus, it would have been *prima facie* obvious to use the compounds of Gyorkos including (Benzyloxycarbonyl)-L-valyl-N-[1-(2-[-(3-methylbenzyl)-1,3,4-oxydiacetyl]carbonyl)-2-(S)-methylpropyl]-L-prolinamide knowing that it has AAT activity in the method of Lezdey with the expectation of success.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Myron G. Hill whose telephone number is 571-272-0901. The examiner can normally be reached on 9am-6pm Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 1648

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Myron G. Hill
Patent Examiner
February 8, 2004


JAMES HOUSEL 2/9/04
SUPERVISORY PATENT EXAMINER
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